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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/127,138	07/31/98	GRUENBERG	M 24731-500E

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EXAMINER

SCHWADRON, R

ART UNIT

1644

PAPER NUMBER

/6

DATE MAILED: 09/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/127,138

Applicant(s)

Gruenberg

Examiner

Ron Schwadron, Ph.D.

Group Art Unit

1644



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 18-21, 46-54, 68-71, 73-135, and 153 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 18-21, 46-54, 68-71, 73-135, and 153 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Supervisory Patent Examiner Christina Chan, at 703-308-3973. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 18-21 are drawn to a method of autologous cell therapy, classified in Class 424, subclass 534.

II. Claims 46,47,52,54,71,106-117,134,131-133,153 are drawn to a method of treating infectious disease, classified in Class 424, subclass 204.1.

III. Claims 50,68,69,73-93,99-101 are drawn to a method of treating autoimmune disease, classified in Class 424, subclass 93.71.

IV. Claims 52,71,102-105 are drawn to a method of treating allergy, classified in Class 424, subclass 275.1.

V. Claims 53,70,94-98 are drawn to a method of treating transplant rejection, classified in Class 424, subclass 93.7.

VI. Claims 71,106-117,134,135 are drawn to a method of treating tumors, classified in Class 424, subclass 277.1.

VII. Claims 71, 118-123 are drawn to a method of vaccination, classified in Class 424, subclass 184.1.

VIII. Claims 48,49,51,124-130 are drawn to a method of altering the regulatory balance of cells, classified in Class 424, subclass 93.3.

3. The inventions are distinct, each from the other because of the following reasons.

4. Inventions I-VIII are different methods. These inventions require different ingredients and process steps to achieve different goals. Inventions II-VI are methods of treating disease wherein methods I, VII and VIII do not recite that disease is treated. Regarding the methods of Inventions II-VI, said inventions use cells derived from different pathologic conditions wherein the cells are structurally and functionally unique (eg. cells that recognize allergens, versus cells that recognize pathogens, versus cells that recognize tumors, etc). The cells of inventions II-VI are given to different types of patients that are suffering from the particular types of disease recited in the claims. The methods of Inventions I, VII and VIII are performed for different reasons that are recited in the respective claims. Therefore they are novel and unobvious in view of each other and are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VIII is not required for any other group from Groups I-VIII and Groups I-VIII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. The following species election is required. Applicant is required to pick a particular disease recited in the claims if the Invention selected recites the treatment of more than one specific disease. If the claimed invention recite uses of regulatory versus effector cells, then applicant is required to pick one or the other. If the claimed invention recites Th1 or Th2 or Th3, then applicant is required to pick one of the aforementioned. If the claimed invention recites CD4 or CD8 positive cells then applicant is required to pick one of the aforementioned.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an

election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 (600)



Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
September 22, 1999



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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